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03-17-02
PATENT

Attorney Docket No. 5540-1A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Vandepopuliere et al	)	Examiner: A. Weier
Serial No.: To be assigned	)	Group Art Unit: 1302
Filed: 19 December 1996	)	
For: METHOD OF CONTROLLING *SALMONELLA* IN SHELL EGGS	)	Date: January 7, 1997

COPY OF PAPERS ORIGINALLY FILED

RULE 132 DECLARATION OF HERSHELL R. BALL, JR.

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

I, Hershell R. Ball, Jr., do hereby declare and say as follows:

1. I received my B.S. degree in Poultry Science from Texas A & M University in 1963. I received my M.S. degree in Poultry Science from Texas A & M University in 1966, and my Masters Thesis investigated the physical and functional properties of gamma irradiated liquid egg white protein. I received my Ph.D. in Food Science from the University of Missouri in 1970, and my dissertation examined the catalase activity that's native to egg whites.

2. From 1970 to until September 1, 1992 I was an assistant professor, then an associate professor, then a full professor, and finally professor *emeritus*, consecutively, in the Department of Food Science at North Carolina State University. Thereafter, until 1994, I was engaged in independent consulting. From April 1, 1994 to the present I have been the Vice President of Research and Development at the M.G. Waldbaum Company. M.G. Waldbaum Company is a subsidiary of Michael Foods, which is the exclusive licensee of the invention claimed in United States Application No. 08/178,734 (the "'734 Application").

3. From approximately 1990 to the present, I have served on the Editorial Boards of the Poultry and Avian Biology Review and the World's Poultry Science Journal. Previously, I have served on the Editorial Board for both the Poultry Science Association's Journal of Poultry Science and the CRC Critical Reviews in Poultry Biology and Journal of Muscle Foods. Professional awards I have received include the Institute of Food Technologists Industrial Achievement Award in 1994 and the Poultry and Egg Institute of America Research Award in 1981. I have published over 30 papers, over half of which relate to eggs or egg products.

4. I am a member of the Institute of Food Technologists which is the principal professional/technical organization in the food science industry. Additionally, I have at various times served as a director of the Poultry Science Association, Chairman of the North Central Regional Research Committee, and Chairman of the American Egg Board's Technical Advisory Committee, and I am a member of numerous other professional organizations.

5. There has long been a concern over microbial contamination of shell eggs sold to consumers. In particular, the discovery of *Salmonella enteritidis* in shell eggs has given rise to alarm by both the food and health industries. To the best of my knowledge, prior to the development of the invention claimed in the '734 application, there were no commercially practiced methods of pasteurizing intact shell eggs so as to reduce *Salmonella* contamination to safe levels.

6. Coagulation can be defined as a change from a sol (fluid) state to a solid or semisolid state. With respect to eggs, coagulation is caused by a change in the physiochemical characteristics of egg protein that results in a loss of solubility and coalescing of the egg proteins, which results in a thickening of the egg white or yolk. As used in the egg industry, coagulation indicates both a loss of solubility and loss of fluidity.

7. Coagulation of egg protein can be effected by many factors including heat, mechanical means (*e.g.*, whipping), salts, acids, or alkalies. Coagulation is also positively

related to protein concentration. In addition, protein coagulation is dependent upon the protein composition of the liquid. With respect to egg proteins, for example, conalbumin and ovalbumin are highly sensitive to coagulation by heat, whereas ovomucoid and ovomucin are noncoagulable by heat. Furthermore, the presence of non-protein components will also alter the rate of protein coagulation.

8. There have been many studies directed at understanding the mechanism of egg protein coagulation. It is currently believed that there is first an unfolding (*i.e.*, denaturation) of protein molecules followed by aggregation to form a solid. Thus, denaturation and coagulation of proteins are distinct concepts. Some investigators have concluded that it is the formation of intermolecular hydrophobic bonds, hydrogen bonds, and disulfide bonds between denatured protein molecules that leads to protein insolubility and solid formation.

9. Heating of egg proteins accelerates the unfolding or denaturation of the egg proteins, thereby increasing the rate and extent of coagulation. Coagulation of egg proteins by heat is an irreversible process. Coagulation is accelerated with incremental increases in temperature.

10. Coagulation of egg proteins can be measured by several means. The most widely used index of coagulation is protein solubility. Protein solubility can be assessed by measuring the rate and amount of coagulum formation. Alternately, the stress required to pull apart coagulated protein samples can be measured. As another indicator of coagulation, one can determine the depth of penetration of a standardized steel ball into a coagulated protein sample. As yet another approach, the force required to penetrate a coagulated protein sample with a plunger can be measured. For coagulated egg products, such as custards, it may also be useful to assess the degree of "sag" in the final coagulated product.

11. Coagulated egg products are essentially solidified. Examples of coagulated egg products include custards, puddings, and cooked eggs (*e.g.*, scrambled eggs, omelettes, fried eggs, soft and hard boiled eggs).

12. Eggs can be whipped to form "soft peaks" or "hard peaks." Thermal treatment of shell eggs often results in a loss of whip volume or an increase in whip time. Thermal treatment has an adverse effect on whip volume and whip time because of thermal denaturation of egg protein. Loss of whip volume or increased whip time does not indicate coagulation of the egg protein, although eggs that are heated to the point of coagulation will not whip up at all because of the loss of fluidity.

13. The invention claimed in the '734 application provides a means of thermally treating intact shell eggs so as to reduce *Salmonella* levels without detrimental effects to egg function or quality such that the treated eggs would be objectionable to consumers. Any visible coagulation in thermally treated eggs would render the eggs commercially unacceptable. With particular regard to coagulation, there is no visible coagulation of either the egg white of the egg yolk in shell eggs treated according to the '734 invention. The treated eggs retain their liquid character. In some instances, thermal treatment results in an somewhat opaque appearance to the egg white, indicating that the egg white protein was affected (*i.e.*, partially denatured) by thermal treatment, but there is no coagulation of either the egg white or the egg yolk.

14. M.G. Waldbaum Company submitted its commercially-produced in-shell pasteurized eggs for testing by an independent test kitchen. These eggs were pasteurized in shell by thermal treatment according to the '734 application. The test kitchen compared the in-shell pasteurized eggs with unheated shell eggs for function and quality. In the report compiled by the test kitchen (attached hereto), it was concluded that there was no difference between thermally treated and unheated shell eggs with regard to flavor, texture, appearance, and overall quality. The only difference observed was that thermally treated shell eggs had a longer whip time as compared to unheated eggs.

15. M.G. Waldbaum Company has been selling in-shell pasteurized eggs, which are thermally treated according to the '734 invention, in a test market within Minnesota since April 1996. The eggs are sold to consumers in cartons in the retail section of supermarkets. Retail sales of in-shell pasteurized eggs according to the '734 invention have been

approximately 3500 to 4000 dozen per week. It is believed that most of the consumers purchasing the thermally treated eggs are repeat customers, indicating consumer satisfaction with the product.

16. Consumers purchasing thermally treated shell eggs utilize them as they would unheated eggs. Any visible coagulation in the thermally treated eggs would be objectionable from a consumer standpoint. In some instances, some opaqueness is observed in the egg white of thermally treated eggs according to the '734 invention, but we do not observe any visible coagulation of either the egg white or the egg yolk.

17. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Hershell R. Ball, Jr.

Hershell R. Ball, Jr.

Jan. 3, 1997

Date

Attorney Docket No. 5540-1A PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Vandepopuliere et al.
Serial No. 08/769,579 Group No. 1302
Filed: December 19, 1996 Examiner: A. Weier
For: METHOD OF CONTROLLING SALMONELLA IN SHELL EGGS

COPY OF PAPERS ORIGINALLY FILED

Assistant Commissioner for Patents
Washington, DC 20231

SUPPLEMENTAL RULE 132 DECLARATION OF HERSHELL R. BALL, JR., Ph.D.

Sir:

I, Hershell R. Ball, Jr., do hereby declare and say as follows:

1. I am familiar with the work described in United States Application Ser. No. 08/769,579 to Vandepopuliere et al. ("the '579 application"). As described in my previous Declaration under 37 CFR § 1.131, I carried out some of the analysis described in the '579 application. In addition, I am currently the Vice President of Research and Development at the M.G. Waldbaum Company. M.G. Waldbaum Company is a subsidiary of Michael Foods, which is the exclusive licensee of the invention claimed in the '579 application.

2. The '579 application describes investigations that have led to the successful pasteurization of intact shell eggs, without significant loss of egg quality or function.

3. I have read United States Patent No. 5,431,939 to Cox et al. ("the '939 patent"), and I am familiar with the work of these investigators. Examples 1 and 3 of the '939 patent do not demonstrate pasteurization of shell eggs by the application of thermal treatment. In Example 1, there was no attempt by Cox et al. to determine *Salmonella* kill following heat treatment. The studies described in Example 3 of the '939 patent are flawed for lack of proper controls, and no conclusions regarding

Salmonella kill can be drawn therefrom. In Example 3, Cox et al. applied thermal treatment to eggs "selected for obvious surface filth, i.e., fecal matter, blood streaks, smudges, feather adherence and the like." ('939 Patent, Col. 17, lines 23-25). Presumably, unclean eggs were chosen in an attempt to select eggs that were infected with *Salmonella*. However, there are no data indicating whether the eggs were, in fact, infected. This may explain why the data are so variable. Nor are any data presented demonstrating a reduction in *Salmonella* by the applied thermal treatments.

4. The recognized standard method for evaluating the efficacy of *Salmonella* kill is a controlled study in which a known quantity of *Salmonella* is inoculated into the egg, and *Salmonella* kill is measured following treatment. In this type of study, one would select clean eggs and carry out the experiments under aseptic laboratory conditions. In addition, a large *Salmonella* dose is inoculated so as to minimize the effects of any endogenous *Salmonella* infection in the egg. Using a controlled inoculation study, one can draw meaningful conclusions regarding the efficacy of *Salmonella* kill. Such controlled experiments were carried out in the studies described by Examples 1-4 of the '579 application.

5. In contrast, Examples 1 and 3 of the '939 patent provide no data whatsoever indicating that *Salmonella* is destroyed by the applied thermal treatments. The microbial data in Table I are completely meaningless. There is no way of knowing whether Cox et al. achieved any decrease in microorganisms as a result of thermal treatments. A reading of "0" or "200,000" in Table I says absolutely nothing about *Salmonella* kill because there is no way of knowing what the initial *Salmonella* counts were. Moreover, it is not even clear whether the microorganisms they are measuring are *Salmonella* or some other microorganism(s). Thus, no conclusions regarding *Salmonella* destruction in shell eggs can be drawn from the studies described in Examples 1 and 3 of the '939 patent.

6. Furthermore, the '939 patent suggests that the "target temperature" for *Salmonella* kill is 130° F at the center of the egg for 2.5 minutes (*see, e.g.*, Col. 7,

lines 62-64 and Col. 16, lines 16-17), however, this statement is incorrect. We have found that at least 136° F for 5 minutes at the center of the egg is required for a one log reduction in *Salmonella*. Pasteurization requires thermal treatments that achieve a temperature of 136° F for at least 30 minutes at the center of the egg. Accordingly, the standard for pasteurization employed by the '939 patent is invalid.

7. The only data in the '939 patent relevant to *Salmonella* kill in intact shell eggs by thermal treatment are provided in Figure 10. The '939 patent indicates that thermal treatments at or above the line corresponding to *Salmonella* destruction (open circles) of Figure 10 are required to achieve *Salmonella* kill in shell eggs. The treatments indicated in Figure 10 of the '939 patent are more severe than those employed in the '579 application. The investigations described in the '579 application have demonstrated that thermal treatments below the *Salmonella* destruction line of Figure 10 of the '939 patent (which is identical to the "Expected Salmonella" line in Figure 1 of the '579 application) are optimal to pasteurize shell eggs. The severe thermal treatments recommended by the '939 patent are likely to result in an inferior product (*i.e.*, will have detrimental effects on the quality and function of treated eggs). In contrast, the '579 application has identified a critical range of thermal treatments that may be employed to pasteurize shell eggs without unacceptable changes in egg quality and function.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Hershell R. Ball, Jr.
Hershell R. Ball, Jr., Ph.D.

June 16, 1998
Date

Attorney Docket No. 5540-1A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Vandepopuliere et al.
Serial No. 08/769,579
Filed: December 19, 1996
For: METHOD OF CONTROLLING SALMONELLA IN SHELL EGGS

Group No. 1302
Examiner: A. Weier

Assistant Commissioner for Patents
Washington, DC 20231

DECLARATION OF DR. HERSHELL R. BALL, JR. UNDER 37 CFR § 1.131

Sir:

I, Hershell R. Ball, Jr., hereby declare and say as follows:

1. I am presently the Vice President of Research and Development at M.G. Waldbaum Company. M.G. Waldbaum Company is a subsidiary of Michael Foods, which is the exclusive licensee of the invention claimed in United States Application No. 08/769,579 (the "`579 application"). At the time the work described below was performed, I was a Professor *emeritus* in the Department of Food Science at North Carolina State University and was also engaged in independent consulting.

2. Prior to 22 November 1993, the filing date of United States Patent No. 5,589,211 to Cox et al., I investigated the work done by Dr. Joseph Vandepopuliere at the University of Missouri-Columbia for Michael Foods. At that time, Michael Foods was considering licensing the '579 technology from the University.

3. As a result of this interaction, Dr. Vandepopuliere and I collaborated in writing a manuscript based on his work demonstrating that *Salmonella* infection could be eliminated from intact shell eggs by thermal treatment. A draft of this manuscript is attached hereto at Tab 1. The draft manuscript was complete and forwarded to the University of Missouri prior to 22 November 1993.

4. It is my understanding that the equivalent time and temperature analysis of Dr. Vandepopuliere's data, described in Example 3 and Table 2 of the '579 application, was performed by Ashwini Kumar, a graduate student at North Carolina State University. The results of Dr. Kumar's analysis are shown at Tab 2. The equivalent time and temperature analyses were complete and provided to me by Dr. Kumar prior to 22 November 1993.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Hershell R. Ball, Jr. — Hershell R. Ball, Jr., Ph.D.

1-26-98 — Date

Attorney Docket No. 5540-1A

PATENT

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Hershell R. Ball, Jr.
Hershell R. Ball, Jr., Ph.D.

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Date